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10/567,424

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John Charles Mulley

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EXAMINER

KOLKER, DANIEL E

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

02/11/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,424

Applicant(s)

MULLEY ET AL.

Examiner

Daniel E. Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18,30-37 and 86 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-16,30-37 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/27/06,5/24/06,8/20/07,10/29/10.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The remarks filed 7 December 2010 have been entered. No claim amendments were presented. Claims 8-18, 30-37, and 86 are pending.

Election/Restrictions

2. Applicant's election of Group I in the reply filed on 7 December 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 December 2010.

4. Claims 8-16, 30-37, and 86 are under examination and will be searched to the extent they encompass the elected invention, namely mutations in SCN1A as in claims 8 and 33, and SEQ ID NO:1-9.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 2003904154, filed in Australia, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The foreign priority document lists certain mutations, for example at p. 71 (Table 1). However none of the

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mutations listed in independent claims 8 and 33 is disclosed in that table, or in any other part of the foreign priority document. The foreign priority document fails to provide evidence that applicant was in possession of every element of claims 8 and 33, and all dependent claims, as of the date it was filed. Therefore the effective filing date of each of claims 8-18, 30-37, and 86 is 6 August 2004, the date that international application PCT/AU2004/001051 was filed.

Should applicant disagree with the examiner's factual determination above, applicant should provide evidence that the foreign priority document discloses every element of the invention now claimed. This could be accomplished, for example, by pointing to specific page and line numbers where each of the mutations is listed within the foreign priority document.

Information Disclosure Statement

6. The information disclosure statements of record have been considered. Note that for the IDS filed 29 October 2010, reference 7 has been crossed out as it is not a valid U.S. Patent Document number. It is one digit shorter than the other publications, and the examiner cannot determine the correct identifier.

Claim Objections

7. Claims 8-16, 30-37, and 86 are objected to because of the following informalities: the claims recite non-elected subject matter, particularly mutations beyond those in SCN1A and SEQ ID NOs:10-72. Appropriate correction is required.

8. Applicant is advised that should claim 9 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-35, 37, and 86 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 31, 37, and 86 are each drawn to

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cells or polypeptides, and are not limited to isolated forms of those products. The claims read on cells that express mutant polypeptides, residing within human patients, as well as the polypeptides themselves. The claims are drawn to products of nature, which are non-statutory. Amending each of claims 31, 37, and 86 to recite "isolated" would be sufficient to overcome this rejection.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11-14, 30-37, and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of independent claims 8 and 33 refers to mutations within SCN1A sequences, either at the nucleic acid or protein level, by referring to specific nucleotide or amino acid numbers. However, as there is no reference sequence, for example in the form of a complete sequence of a wild-type nucleic acid or protein, it is impossible to discern what the specific base or residue numbers correspond to. Referring to the 664th or 1152nd nucleotide, for example, simply makes no sense when a full-length sequence is not also listed. One of skill in the art could not determine what the specific numbers refer to, and therefore each of claims 8 and 33 is vague and indefinite. The remaining claims depend either directly or ultimately from these claims and therefore are indefinite as well.

Claims 12 and 14 are also indefinite as they recite the language "including but not restricted to". This language indicates that although the disorders listed in the claims are to be considered, other non-enumerated disorders are also part of the invention. One skilled in the art could not determine which diseases or conditions are associated with the mutation, and could not determine what constitutes the boundaries of patent protection. Changing the language to "selected from the group consisting of" would be sufficient to overcome this aspect of this rejection.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11-14, 30-32, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace, WO 02/50096, published 27 June 2002, cited as reference 29 on IDS filed 29 October 2010.

Wallace teaches isolated nucleic acid encoding a sodium channel 1A subunit, wherein base 664 has been changed from C to T. See for example SEQ ID NO:89, beginning on p. 128 of the sequence listing of the Wallace publication, as well as p. 4 lines 8-9. Claims 11-14 are included in this rejection as they recite no additional structural features, and since the mutation is present it necessarily leads to disruption of an ion channel to produce the recited effects. Claims 30-32 are anticipated as Wallace also teaches vectors and host cells with the nucleic acid; see p. 6 lines 14-36. Claims 36-37 are anticipated as Wallace teaches preparing the protein by the steps recited in claim 36; see for example p. 6 line 37 – p. 8 line 17.

12. Claims 8-16, 30-31, 33, 36-37, and 76 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suguwara May 2003 (Epilepsy Research 54:201-207, cited as reference 156 on IDS filed 29 October 2010).

Suguwara teaches nucleic acids encoding R1470X and R1892X mutations in sodium channel 1A proteins. See for example p. 202, section 2.2. The reference is silent as to the exact changes at the nucleic acid level which encode these mutations. However, the triplet genetic code is well-known (note the present specification refers to the triplet code as "the standard triplet genetic code"; p. 19 lines 13-14). The R1470X and R1892X mutations are either inherently in the nucleic acids taught by Suguwara, or they are obvious variants thereof, as one of skill in the art would have immediately known the very few possible mutations at the nucleic acid level which would lead to R → X mutations. Therefore the reference either actually teaches, or renders obvious, claim 8, which encompasses nucleic acids which encode these particular mutations. Claims 9, 10, 15, and 16 are included in this rejection as well; SEQ ID NO:9 is a nucleic acid that is identical to that which encodes wild-type SCN1A with the exception that there is a C5674T substitution. As explained above, this is either the same as that disclosed by Suguwara or an obvious variant thereof.

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Claims 11-14 are included in this rejection as they recite no additional structural features, and Suguwara teaches that the lead to disrupted sodium channels. Claims 30-31 are anticipated as the reference teaches placing the nucleic acids into vectors and transfecting into cells (paragraph spanning pp. 202-203). Claim 33 is anticipated as the reference teaches cells comprising functional ion channels with the mutants incorporated in (p. 203 section 2.4 and Results). Claims 36-37 and 86 are anticipated as Suguwara teaches culturing cells for 20-36h and then isolating the protein on a Western blot (p. 203 first paragraph).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel E. Kolker whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E Kolker/

Primary Examiner, Art Unit 1649

February 9, 2011